

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Greenberg, et. Al.

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Serial No.:

09/976,799

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Oropeza

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09/976,799

For:

Package for an Implantable Medical Device

Assistant Commissioner For Patents Washington, D.C. 20231

DECLARATION OF DAO MIN ZHOU

Dear Sir:

I, Dao Min Zhou, state and declare:

- 1. I am an Employee of Second Sight Medical Products, Inc ("Second Sight"). My title is Senior Electrochemist. I earned a PhD in Chemistry from University of Ulster, UK. I have more than 15 years experience in the R&D and testing of biomaterials in various biomedical research institutes and industries from UK, Ireland, France, Canada and USA. I am not an inventor on the above referenced patent application.
- As part of my work for Second Sight, I test materials for hermetic properties and biocompatibility, in preparation for their use in implantable medical devices. I am familiar with all of the experimental materials discovered by Second Sight employees for use in implantable medical devices.
- 3. At the request of Scott Dunbar, I reviewed US Patent 5,109,844, and in particular, its description of growing silicon dioxide (SiO₂) on integrated circuits.
- 4. I am familiar with the process of growing SiO₂ on silicon integrated circuits to act as a passivant. This process is commonly used to prevent further oxidation of the integrated circuits when exposed to air. It is completely inadequate to protect integrated circuits when exposed to saline, which has sodium chloride and other ions, and at 100% humidity. Saline dissolved SiO₂ at a much slower rate than that etch solutions used to

remove SiO₂ in the semiconductor industry, but faster enough to dissolve a thin layer of SiO₂ and cause general and pitting corrosion during a prolonged soak period. With a few months soak, the SiO₂ will be attacked by sodium chloride and hydroxyl ions. The dissolution rate reached 1.7-3.2 micrometer (17,000-32,000 Angstroms) per year in the physiological saline at 37°C. The chemical dissolution mechanism is believed to be the hydration and complex formation reactions, [pp151-165, in *Electrochemistry of Silicon and its oxide*, by X.G. Zhang, Kluwer Academic/Plenum Publishers, New York, 2001]. The external surface of an oxide is a hydrate and acts as a proton donor or acceptor. This hydrated surface forms complexes with sodium, chlorine and hydroxyl ions and generates soluble complex products. At only 5,000 thick, silicon dioxide is not hermetic (even if it were hermetic, dissolution of SiO₂ would generate pits to have the inner Silicon exposed), and would offer only limited resistance to the migration of saline in to the underlying silicon substrate.

- 5. Further, the selective etching process, as described in US Patent 5,109,844, would breach any limited sealing properties provided by the silicon dioxide layer.
- 6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and, further that these statements are made with knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Respectfully submitted,

Date

Dao Min Zhou PhD

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